BUREAU OF RADIATION CONTROL
REGULATORY GUIDE
TEXAS DEPARTMENT OF HEALTH

REGULATORY GUIDE 3.1

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE MEDICAL USE OF RADIOACTIVE MATERIAL

I. Introduction

This guide describes the type of information that the Texas Department of Health, Bureau of Radiation Control (agency) staff needs to evaluate a license application for the limited medical use of radioactive material.

An application for medical uses of radioactive material must be submitted in duplicate on BRC Form 252-2a, "Application for Radioactive Material License - Human Uses." Pages 3 and 4 of BRC Form 252-2a, the Preceptor Statement, must be submitted for each physician desiring to use radioactive material. Applications for amendments to existing radioactive material licenses may be submitted on BRC Form 252-2a or in a letter stating the same information as specified on that form. The applicant should retain a copy of all submitted documentation since once the application has been approved, the licensee will be committed to operate under the approved submitted documentation.

II. License Fees

An application fee is required for all specific licenses and must be submitted with any NEW application. The applicant should refer to 25 Texas Administrative Code (TAC) §289.204 (relating to Fees for Certificates of Registration, Radioactive Material(s) Licenses, Emergency Planning and Implementation, and Other Regulatory Services) [Part 12 of the Texas Regulations for Control of Radiation (TRCR)] to determine the fee that should accompany the application. Review of the application will not begin until the proper fee is received by the agency. The check or money order should be made payable to the Texas Department of Health.

A fee should NOT be submitted with the application for a request for renewal or amendment. All current licensees will be billed according to the expiration month of their current license.

III. Instructions For Completing The Application

The separate items of the application are discussed below:

Item 1 - If a physician is requesting the use of radioactive material at the physician's own practice, then the legal name of the physician's practice should be used as the applicant. If radioactive material is to be stored and used at an institution, the institution is named as the applicant. This guide covers the typical use of radioactive material at a medical institution. Additional documents provide guidance for the preparation of applications for specific uses of radioactive materials such as eye applicators, bone mineral analyzers, xenon, remote control brachytherapy devices, and blood irradiators. These regulatory guides are available from the agency upon request. Some uses, such as teletherapy, may require a separate license.

Items 2 through 4 - Self explanatory.

Item 5 - List physician users and board certification. (See item 10 to describe required and suggested minimum training requirements).

Item 6 - List name and telephone numbers of the Radiation Safety Officer (RSO). (See item 10 to describe minimum training requirements).

Item 7 - Radioactive Material Information.

A. Group Uses - See §289.252(w)(2) (relating to Licensing of Radioactive Material) [TRCR Appendix 41-B], "Groups of Medical Uses of Radioactive Materials." Check the appropriate box if group uses are desired. If the physician user applicant has appropriate experience in the diagnostic use of radioactive materials (See §289.252(w)(5) [TRCR Appendix 41-E], "Acceptable Training and Experience for Medical Uses of Radioactive Material"), he/she may request all routine diagnostic uses by group number. Group I comprises those uptake, dilution, and excretion studies for which the United States Food and Drug Administration (FDA) has accepted a New Drug Application (NDA). Group II comprises all routine NDA imaging and tumor localization studies. Group III comprises all routine NDA radioisotope generators and all routine NDA reagent kits used to prepare radiopharmaceuticals. (If more than 2 curies of generator activity is needed or if a generator other than molybdenum/technetium (Mo/Tc) will be used, explain on a separate sheet.)

NOTE: Investigative uses (INDs), therapeutic uses, gas and aerosol uses, and calibration and check sources other than those authorized by §289.252(f)(2)(D) [TRCR 41.26(b)(4)], "Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material," are not authorized by the groups listed in §289.252(w)(2) [TRCR Appendix 41-B], and must be specifically authorized as a line item on the license.

B. Additional Items Desired.

1. Under (a), list isotope, i.e., "iodine-131," "cobalt-57," etc.

2. Under (b), list each chemical and/or physical form of isotope. (If source is a sealed source, state the manufacturer and model number.)

3. Under (c), list maximum amount of material to be authorized in millicuries at any one time for each form of radiopharmaceutical or in each sealed source.

4. Under (d), for radiopharmaceutical, give the procedure to be performed. Examples: hyperthyroid therapy, instrument reference source.

Items 8 and 9 - Self-explanatory.

Item 10 - Training of Authorized Physicians, Radiation Safety Officer, Technologists, and Others.

A. Authorized Physicians - To use radioactive material in humans, an individual must be licensed in accordance with the laws of the state of Texas to dispense and use drugs in the practice of medicine, and have basic and clinical radioisotope training and experience commensurate with the proposed use of radioactive material. Training and experience are specified in §289.252(w)(5) [TRCR Appendix 41-E]. If a physician has been authorized within the past five years on another Texas radioactive materials license, evidence of this authorization may be submitted in lieu of training descriptions. This should include the license number, specific authorizations, and dates of practice.

B. Radiation Safety Officer (RSO) - The RSO is the person designated to be responsible for the day-to-day radiation safety program. The RSO maintains all records required by agency rules and is also the primary contact with the agency on matters pertaining to the license and the use of radioactive materials. The RSO's training and experience with the types and quantities of radioactive materials for which a license is being requested must be submitted. Qualifications may be found in §289.252(g) [TRCR 41.27], "Radiation Safety Officer."

C. Technologists - All personnel who will be authorized to handle radioactive material must be qualified through training and experience to use the material in question for the purpose requested, and in such a manner as to minimize danger to public health and safety or the environment. Multi-modality operations authorized under a single license may require several descriptions, each unique to the delegated specialty tasks (therapy, diagnostic imaging, *in vitro*).

[**NOTE:** The word technologist, defined as someone delegated to by a medical doctor, will be used synonymously with any delegation within the following career fields: physicist, dosimetrist, nurse, or physician's assistant. Note that in addition to meeting commitments to the agency for training criteria, final technologist approval should always rest with the physician who is obligated to supervise and is ultimately responsible for the performance of all clinical tasks he/she has delegated.]

D. Suggested minimum training for technologists handling diagnostic radiopharmaceutical. Submit documentation of the following:

Individuals must be certified as a general certificate medical radiologic technologist (MRT) under Texas Civil Statutes, Article 4512m. In addition each individual must:

1. be certified by the Nuclear Medicine Technologist Certification Board (CNMT); or

2. be certified in nuclear medicine by the American Registry of Radiologic Technologists [ARRT(N)]; or

3. be board eligible to take the CNMT or ARRT(N) examinations; or

4. have graduated from an approved Joint Review Committee on Educational Programs in Nuclear Medicine Technology (JRCNMT) program or be a student who is supervised and operating within such a program. (Contact JRCNMT at 801-364-4310 to verify approved programs); or

5. demonstrate grandfathering as an MRT based on two years of full-time nuclear medicine experience; or

6. have performed full-time nuclear medicine for a minimum of two years during the past five-year period. This experience must be certified in writing by an authorized physician user; or

7. have completed training in accordance with the outline in Appendix H, "Sample of a Minimum Radiation Safety Training Outline for Radiation Handlers." **NOTE:** If hiring an individual with this type of documentation, the prior training could be considered acceptable without need for additional training if the scope of practice was equivalent to that of the original training site.

Item 11 - Facilities. Provide a brief description of the anticipated numbers of procedures per month (separate diagnostic from therapeutic), technologists employed, cameras in operation, and rooms of use. Provide a full page drawing of each room of use and describe the uses in each room. Temporary brachytherapy and/or temporary injection sites, e.g., x-ray rooms and patient rooms, need not be identified. Only use locations that are fully described will be authorized by the license, so areas such as nuclear stress labs, storage areas, in vitro labs, etc., will need to be included if radioactive material is periodically brought into these areas. See suggestions in Appendix E, "Facility Design Considerations for a Hospital's Nuclear Medicine Department." Identify all fixed radiation detection equipment, work counters, safety equipment, shielding, and other areas of use or storage. Also provide a facility floor plan that identifies and shows the location of each of the routine sites of use and its surroundings.

Item 12 - Operating, Safety, and Emergency Procedures. Submit an Operating, Safety, and Emergency Procedures Manual. (See Appendix A, "Items to be Included in an Operating, Safety, and Emergency Procedures Manual.")

NOTE: This manual may serve as a basis for a radiation protection program in accordance with §289.202(e).

Item 13 - Radiation Detection Instrumentation - Self-explanatory.

Item 14 - The application must be signed and dated by the applicant or an individual duly authorized by the applicant to act for or on the applicant's behalf. Unsigned and undated applications will be returned to the applicant. Retain one copy for your files and mail two copies of the license application, supporting documentation, and appropriate fee to:

Texas Department of Health
Bureau of Radiation Control
1100 West 49th Street
Austin, Texas 78756-3189

APPENDIX A

ITEMS TO BE INCLUDED IN AN OPERATING, SAFETY, AND EMERGENCY PROCEDURES MANUAL

The following items should, as a minimum, be included in an operating, safety, and emergency procedures manual. Use of a table of contents and serially numbered pages will assist in communications between the applicant/licensee and the agency.

1. Describe how the authorized physician user orders a diagnostic or therapeutic procedure and how it is documented.

2. Describe delegating physician supervision of technologists in the proposed setting (e.g., laboratory) . Establish a minimum frequency of supervision that will be documented (e.g., no less than monthly). Standards would likely be different based on minimum qualifications, workload, and scope of program (e.g., technologists working from a well-documented clinical procedures manual versus always working in the presence of the physician).

3. Delineate all major clinical or radiation safety tasks that are likely to be delegated by an authorized physician user to someone else, listed separately by various specialties where multi-modal operations are licensed. Do not overlook the ordering and packaging of radioactive material, patient administrations, surveys, inventorying, and removal/sterilization/transportation of therapy sources.

4. Describe the radiation safety program management to include the functions of the RSO and the Radiation Safety Committee (RSC)

    a. RSO - The RSO should assume control and have authority to institute corrective actions, including shutdown of operations when necessary in emergency situations or unsafe conditions. RSO duties are described in §289.252(g) [TRCR 41.27].

    b. RSC - If the scope of the radioactive materials program includes multiple disciplines, the institution should consider establishing a Radiation Safety Committee (RSC) to support the RSO in overseeing the use of all radiation sources throughout the institution. In addition to the RSO, the membership of the committee may include applicable positions from the following: executive management, imaging and laboratory technologists, physician users of each related specialty, nursing, and representation from each permanent additional authorized use location.

5. Describe the program for periodically checking the use of radioactive material to assure that proper safety procedures are followed. A recommended radiation safety audit program that may be used is described in Appendix B, "Recommended Radiation Safety Audit Program."

6. Describe the method of recording receipt, authorized use, transfer, inventory, and disposal of radioactive material. Indicate who is authorized to place orders for delivery of radiopharmaceutical or therapeutic sources.

7. Describe the method for receiving radioactive material, promptly notifying responsible persons, monitoring for contamination, and storing it securely. Receipt of materials (such as generators) after normal working hours should be specifically addressed. (See §289.202(ee) (relating to Standards for Protection Against Radiation) [TRCR 21.906],"Procedures for Receiving and Opening Packages").

8. Describe the method of restricting access to radioactive material to authorized users and other trained workers, including the method of controlling access to restricted areas, radiation areas, and high radiation areas. Describe how associated staff such as housekeeping, transportation, and nursing are trained to comply with §289.203(c) (relating to Notices, Instructions, and Reports to Workers; Inspections) [TRCR 22.12], "Instructions to Workers."

9. Commit to testing and analyzing for leakage sealed sources of radioactive material in accordance with §289.201(g) (relating to General Provisions) [TRCR 11.7], "Tests for Leakage or Contamination of Sealed Sources." If the applicant wishes to test its own sources, the procedures for wiping, counting, converting to microcuries, etc. must be submitted. (Regulatory Guide 5.1, "Guide for the Preparation of Leak Test Applications," may be obtained from the agency).

10. Describe the routine visual and radiation surveys to be made of areas where radioisotopes are used and stored (See Appendix C, "Suggested Methods and Frequency for Conducting Radiation Surveys.") Include frequencies, action levels, instrumentation used, and sample records. If bioassays are required by §289.202(i) and (q)(3) [TRCR 21.204 and 21.502(c)], "Determination of Internal Exposure" and "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," describe the process. Additional guidance may be requested from the agency. If any duties are subcontracted, describe the tasks and confirm that these activities will be reviewed by the RSO, the RSC, and as part of the annual review required by §289.202(e) [TRCR 21.101], "Radiation Protection Program."

11. Describe the method of monitoring personnel exposure. Note that ring badges may be required for persons handling millicurie amounts of activity. (See §289.202(q)(1)(A) and (q)(1)(B) [TRCR 21.502(a)(1) and (3)]. See §289.202(p)(3) [TRCR 21.501(c)], "General Surveys and Monitoring," for supplier accreditation requirements. (Regulatory Guide 5.4, "Personnel Monitoring Services," lists authorized suppliers and is available from the agency upon request.)

12. Describe general laboratory procedures for preventing contamination when handling uncontained radioactive material (See Appendix D, "General Guidelines for Safe Use of Radioactive Material in a Nuclear Medicine Laboratory.")

13. Describe methods for coping with spills and personnel contamination, radiation incidents, excessive individual exposures, lost or stolen sources, clinical misadministrations, and significant facility contamination.

    NOTE: Please see the following referenced material for additional information.

    Spills and personnel contamination - Appendix F, "Suggested Methods for Coping With Spills and Personnel Contamination."

    Radiation incidents and excessive individual exposures - §289.202(xx) [TRCR 21.1202], "Notification of Incidents," and §289.202(yy) [TRCR 21.1203], "Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits."

    Lost or stolen sources - §289.202(ww) [TRCR 21.1201], "Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation."

    Clinical misadministrations - §289.201(b) [TRCR 11.2], definition of misadministration, and §289.252(f)(4) [TRCR 41.26(d)], "Records and Reports of Misadministrations."

    Significant facility contamination - §289.252(r) [TRCR 41.60], "Notification of Incidents."

14. Describe the specific method for managing and disposing of radioactive wastes. In order to minimize the amount of radioactive waste, items suspected of being contaminated should be surveyed. Radioactive medical wastes may be disposed of by transfer to a licensed waste disposal firm, by release into a sanitary sewer, by segregation and storage until activity has decayed, or by incineration. Address procedures for collection of all waste streams, including in-patient diapers, and administration supplies (i.e. gloves, needles, tubing). This should include procedures for patients in in-vitro and remote stress labs. See Appendix G, "Radioactive Waste Management."

15. Provide procedures for recommended calibration of dose calibrators to be used in accordance with the manufacturer, the American National Standards Institute (ANSI), or the United States Nuclear Regulatory Commission (NRC). Model procedures patterned after those recommended by the NRC may be found in Appendix H, "Model Procedures for Calibrating Dose Calibrators."

a. Unit dose. When using unit doses, the applicant/licensee should commit to receiving only precalibrated prepared radiopharmaceuticals delivered in their final administration device (e.g., syringe).

NOTE: This commitment means that no modification of contents, volume, and/or container will be made on site. When the administration time deviates from the nuclear pharmacy's pre-calibrated time by 15 minutes or more, the documented activity should reflect mathematical correction accounting for decay.

b. Beta or positron emitters. If beta or positron emitters are utilized, please provide a separate discussion for quantitating those isotopes.

16. State how often and by whom the survey instruments, including well counters and wipe counters, will be calibrated. Describe how corrections are made for the energy of the isotopes being used. (Regulatory Guide 5.2, "Guide for the Preparation of Survey Instrument Calibration Applications," may be obtained from the agency if survey instrument calibration is to be done by the licensee.)

17. If a technetium-99m generator is to be used or if any radiopharmaceuticals are to be prepared from a reagent kit, include the following information in the procedures (if requesting bulk radiopharmaceuticals address only a. through d.):

a. Confirm that finger badges will be worn on the dominant hand by technicians who elute radioisotope generators or prepare kit radiopharmaceuticals.

b. Confirm that the manufacturer's instructions, recommendations, and specifications will be strictly followed when eluting the generators, preparing the kits, and using and storing the resultant radiopharmaceutical.

c. Method of assaying doses that are prepared from the generator and/or kits.

d. Confirm that syringe and vial shields will be used in accordance with manufacturer's recommendations.

e. Name and model of the high range survey meter (up to 1 roentgen/hour capability) that will be used if a generator is to be possessed.

f. If generators are held for decay, confirm that the bare cores are to be monitored for acceptable levels prior to disposal.

g. Confirm that each generator elution will be tested for molybdenum-99 breakthrough, and describe the criteria for assuring that, at injection, acceptable limits are not exceeded (0.15 microcurie molybdenum-99 per 1 millicurie of technetium-99m).

18. If the applicant desires to use xenon-133, describe the systems that will be used to prevent the exhaled or leaked gas from contaminating the environment and the facility. Include procedures on protecting personnel administering the material. (A guide and worksheet may be obtained from the agency upon request.)

    For DTPA as an aerosol, provide the maximum activity to be used in the aerosol generator at any one time, the manufacturer make/model number of the device to be used, confirmation that the manufacturer's protocol will be followed, and disposal procedures for contaminated apparatus.

19. Confirm whether capsule form of iodine will be used. If iodine solutions are to be administered, submit procedures for handling millicurie quantities including provisions for ventilation (fume hoods), covering and shielding containers, and bioassays (thyroid counts). Procedures for minimizing the spread of contamination in the patient's room should also be addressed. (A bioassay guide may be obtained from the agency.)

    NOTE: Iodine capsules can be contaminated and complete survey and handling requirements need to be followed.

20. Commit that an authorized physician user will be present in the facility and be within normal voice range during administration of radiopharmaceutical and sealed source therapy, with the exception of afterloading procedures.

21. Describe procedures for handling, logging in and out, and storing sealed sources used for therapy. Include descriptions of special equipment used to minimize exposure (such as carriers, remote handling tools, L-blocks, etc.) Logs should include identification of source, name of authorized physician, where source is being taken, date and time source is logged in or out, and name of individual logging out source.

22. If radioactive materials are used for therapy, provide sample written nursing instructions (to be placed in patient charts) for each isotope and use. These instructions should assure proper protection of other patients, visitors, and hospital staff. Also, describe a documented training program for all staff attending therapy patients with radioactive material. This training should incorporate question and answer sessions and demonstrations of catheters and dummy sources. Identify trainers, frequency, curriculum, and staff targeted for this training.

23. Describe procedures for performing radiation surveys around patients containing therapeutic quantities of gamma emitting radioisotopes and for restricting the area around each patient. Include procedures for surveying patients and rooms to verify that:

    a. all temporary implants have been removed prior to the patient's release from the hospital.

    b. the release limits on patients containing radiopharmaceutical and permanent implants are in accordance with §289.256(b)(5) (relating to Use of Sealed Radioactive Sources in the Healing Arts) [TRCR 33.2(e)], "Release of Patients Containing Temporary or Permanent Implants."

    c. instructions are provided to patients who receive permanent implants or therapeutic radiopharmaceuticals.

    NOTE: Additional guidance may be found in the National Council of Radiation Protection and Measurements Report No. 37.

APPENDIX B

SAMPLE RADIATION SAFETY AUDIT PROGRAM

Radiation safety audits provide a method for ensuring that proper safety procedures as specified in the licensee's operating, safety, and emergency procedures manual are followed. Specific tasks and frequencies for radiation safety AUDITS in an active department are suggested below. Supervision of radiation workers should include regular and direct observation in all use areas for adherence to general laboratory procedures, As Low As Reasonably Achievable (ALARA) practices, and use of personnel monitoring. Note that while a consultant may play a very important role by assisting the RSO in performing independent audits/inspections, review of required documentation, and assistance with written safety procedures, this individual cannot be delegated responsibility for day-to-day radiation safety. Additionally, the audit should represent the entire radiation safety program, may be compiled by the RSO, and should be presented to the RSC and/or senior management.

1. On a monthly basis, the RSO should ensure the following:

    a. Adherence to site-specific "general laboratory safety procedures."

    b. Timely completion of daily records and equipment testing.

    c. Review of personnel monitoring results against acceptable limits for possible trends.

2. On a quarterly basis, the RSO should review the following documentation:

    a. Surveys (contamination and radiation field) for completeness, frequencies, results, and trends.

    b. Radioactive materials receipt and utilization logs for completeness, legibility, and retention in accordance with §289.201(d) [TRCR 11.4], "Records."

    c. Quality control tests on imaging and analytic detection equipment (thyroid probe, well counter, scalers, rate meters, etc.) against acceptable parameters.

    d. Waste disposal/transfer logs for completeness, documented evaluations, and acceptable methods.

    e. Dose calibrator test results to ensure appropriate time frames and acceptable manufacturer's tolerances are met.

    f. Therapy patient/room-closeout surveys for completeness and acceptable levels.

    g. Employee training records.

h. Monthly audits verifying regular supervision by the RSO and/or delegating physician.

i. Survey meter calibration.

j. Leak test results.

k. RSC meeting minutes.

l. Inventory against licensed sealed sources (make, model, and activity).

m. Posting requirements of §289.202 (z) through (cc) [TRCR 21.901 through 21.904], "Caution Signs," "Posting Requirements," "Exceptions to Posting Requirements," and "Labeling Containers and Radiation Machines," and §289.203(b) [TRCR 22.11], "Posting of Notices to Workers."

n. All records of safety tasks (calibrations, package receipt, monitoring) delegated by the RSO.

3. The RSO should prepare an annual summary report to the RSC and senior management to include the following:

a. Summary of quarterly audits and agency inspections.

b. Identification of any trends in abnormal occurrences or misadministrations.

c. Review of current Operating, Safety, and Emergency Procedures Manual and needed changes. Identification of current needs (equipment, staff, resources, license amendments). Implementation of the documented Radiation Protection Program (RPP).

d. Identification of any other changes to the program.

4. Oversight and quality assurance for sub-contracted tasks.

Be aware that when contractors perform radiation safety tasks (dose calibrator testing, contamination and radiation field surveys), the RSO must ensure that the licensee's approved procedures, frequencies, and specification limits are met.

APPENDIX C

SUGGESTED METHODS AND FREQUENCY FOR CONDUCTING RADIATION SURVEYS

1. Introduction

When radioactive material is received, handled, and/or stored within a medical facility, surveys are required by the rules, are necessary to release areas for unrestricted uses, and/or are needed to assure that both the public and radiation worker exposures are maintained consistent with the ALARA principle.

Area Surveys - Radiation area surveys are performed to assess ambient exposure levels in occupied areas in the vicinity of radiation sources (those stored, being handled, or in patients), to detect or localize contamination, and/or to find lost sources.

Contamination Surveys - Contamination surveys are performed by wiping a surface of specific dimensions and counting the wipe to determine if removable contamination exists. This is done to prevent internal uptake of radioactive material, cross-contamination, deposition of radioactive material in excess of §289.202(ggg)(6) [TRCR Appendix 21-F], "Acceptable Surface Contamination Levels," and/or to render equipment unusable.

2. Frequency of Surveys

a. Narrow scope laboratories - Persons working within restricted areas using no more than microcurie levels of radioactive material or radiopharmaceuticals should perform limited area and personnel surveys at the conclusion of each day of use. No less than once a month, both area and contamination surveys should be performed and documented.

b. Medium scope laboratories - Persons working within restricted and secured areas (imaging or dedicated stress rooms) where millicurie quantities of radioactive material are routinely handled should perform limited area surveys each day of use. Contamination should be checked for in areas like waste baskets, drawers, door or control knobs, keypads, and injection trays. These same areas should have detailed area and removable contamination surveys performed no less than once each week.

c. Full scope laboratories - Persons working within restricted and secured areas (e.g., hot labs) where Mo/Tc generators are used or reagent kits are prepared from bulk technetium eluate, should perform and document area and removable contamination surveys each day of use.

d. Packages labeled with a radioactive white I, yellow II, or yellow III label as specified in United States Department of Transportation (DOT) regulations 49 Code of Federal Regulations (CFR) 172 are required to have receipt and shipping surveys.

e. Rooms and equipment that are occasionally used (remote stress labs or patient rooms) and then released for unrestricted use, must have both contamination and area surveys performed on them to demonstrate compliance with §289.202(eee) [TRCR 21.1303], "Surface Contamination Limits for Facilities and Equipment," and §289.202(ggg)(6) [TRCR Appendix 21-F]. Following a patient administration within a hospital room, only a survey to search for removable contamination would be necessary unless evidence suggests that wide spread contamination may be within that room. Note that if further remedial actions were necessary, it would necessitate removing the patient prior to area surveys due to the high background levels emanating from the patient.

f. Storage areas where inventory is changing often should be surveyed for ambient radiation exposure rates weekly. Once a radiation survey of a storage area has been made, no other radiation surveys are required unless the quantity of radioactive material increases or there has been a structural change to the area. Visual surveys should be performed at least on a quarterly basis.

g. Personnel surveys (otherwise known as frisking) must be performed on individuals' hands and protective clothing after handling non-sealed forms of radioactive material and before leaving a restricted area. Any positive contamination findings should be reported to the RSO and additional area surveys should be performed promptly. It is not necessary to document these surveys unless evidence of contamination has been found.

3. Survey Methods

a Ambient field surveys of radiation exposure rates should be performed with an instrument appropriately calibrated for the radioactive material used in that location and should be documented to reflect the highest radiation exposure rate detected. This should include areas of use, storage, or adjacent areas.

b. Area surveys should be performed in use areas for contamination or lost sources with the most sensitive portable detector available that is appropriate for the radioactive material used in that location. A suggested method is to move the detector slowly and within one inch of surfaces (staff, facilities, equipment), using care not to touch any potentially contaminated objects. Attention should also be given to radioactive markers, syringes, or materials that might have been discarded or placed in unauthorized containers or areas.

c. Removable contamination wipes should be evaluated in a low background area with a detection system with a minimum detection level of at least that of the permissible removable contamination limit. Any surface that is routinely touched while not wearing gloves is a potential location for cross-contamination that can lead to internal deposition.

4. Acceptable Levels - Survey action levels should be established and must be at least as restrictive as standards required by §289 [TRCR]. Action levels should be addressed for the following requirements:

a. Ambient radiation levels in restricted areas must be maintained so as to comply with §289.202(f) [TRCR 21.201], "Occupational Dose Limits for Adults," and reflect ALARA. In public areas, the licensee must comply with §289.202(n) [TRCR 21.301], "Dose Limits for Individual Members of the Public," §289.202(eee) [TRCR 21.1303], and §289.202 (ggg)(6) [TRCR Appendix 21-F]. Note that continuous radiation fields as low as 0.06 milliroentgens/hour could cause a non-radiation worker to receive an annual (2000 working hours) exposure of 120 millirem, which exceeds regulatory limits. Methods to determine exposure to the public in adjacent non-restricted areas must be determined to show compliance with §289.202(o) [TRCR 21.302].

b. Contamination:

(i) Fixed contamination surveys must be performed using a survey instrument capable of detecting and quantifying removable contamination at the licensee's survey action levels. Every location that is frequently touched by radiation workers who might unknowingly cross-contaminate equipment and facilities should be checked. Of particular concern are locations where radiopharmaceutical injection paraphernalia or reference sources might be inadvertently left unattended or accidently discarded. Following brachytherapy implants, surveys should be performed where seeds might have been accidently dropped, sloughed from the body, or collected in drainage tubes or suction canisters. §289.202(ggg)(6) [TRCR Appendix 21-F] establishes a 5000 disintegrations per minute/100 centimeters squared average for fixed contamination.

(ii) Removable contamination surveys must be performed using a survey instrument capable of detecting and quantifying removable contamination at the licensee's survey action levels. Whenever possible, a wipe for contamination should be taken of an area of at least 100 centimeters squared. The wipe should be matched to a specific location in the area being wiped. The results of the evaluation of the wipe must be in units of activity (disintegrations per minute, curies, or Becquerels).

c. See Appendix G, "Radioactive Waste Management."

d. Package surveys must be performed to ensure compliance with §289.202(ee) [TRCR 21.906].

e. Patient release survey levels can be found in §289.256(b)(5) [TRCR 33.2(e)], "Interstitial, Intracavitary, and Superficial Applications" and §289.252(f)(3) [TRCR 41.26(c)], "Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material." Patients undergoing permanent implant therapy may be released from their medical treatment facility when the exposure rate from the patient's implant has fallen to 5 milliroentgens per hour at one meter. Patients undergoing a radiopharmaceutical therapy can be released when the activity within the patient has fallen to less than 30 millicuries **OR** the exposure rate from the patient has fallen to 5 milliroentgens per hour at 1 meter. Care should be taken to use a suitable and calibrated instrument, particularly when dealing with low energy gamma or beta emitting radionuclides.

5. Instrumentation - The licensee must ensure the survey and counting instruments they wish to use are capable of detecting and quantifying removable contamination at the licensee's survey action levels.

a. Waste disposal measurements used to declare the waste as non-radioactive must be performed with an instrument highly sensitive to the types of radiations and the energies of the radiations. A scintillator detector (e.g., probe or unshielded gamma camera) for gamma emitters and a pancake probe for beta emitters possess the sensitivities of choice.

b. Counting equipment used to evaluate wipes for removable contamination must be adequate to meet the action levels to which the licensee is committing. Note that instrument calibration, and in this case, unit efficiency, are required at intervals not to exceed 12 months by §289.202(p)(2) [TRCR 21.501(b)]. Typically a shielded, fixed counting geometry, well-type scintillation detector is used for this low level of detection. Some portable instrumentation will often read in units of counts per minute which must be converted to units of activity (e.g., microcuries or disintegrations per minute).

c. Contamination surveys of staff, equipment, and facilities should be performed with the most sensitive portable detector available. Recommendations for this type of survey would include a scintillation probe (low-energy, thin-crystal or one-by-one crystal) and/or a Geiger-Mueller pancake probe.

APPENDIX D

GENERAL GUIDELINES FOR SAFE USE OF RADIOACTIVE MATERIAL IN A NUCLEAR MEDICINE LABORATORY

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving any restricted area or temporary use location.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances when their use may compromise safe patient administration.

5. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10% unless specifically approved by an authorized physician user.

   b. For all doses, check the patient's name against the written referral, the radionuclide, the chemical form, and the activity against the authorized user's written order and/or standing medical orders.

7. Wear personnel monitoring devices (film badge or thermoluminescent dosimeter) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices, when not being worn to monitor occupational exposures, should be stored in a designated low background area, as should the control badge.

8. Wear thermoluminescent dosimeter finger badges during elution of generator, reagent kit preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially labeled and properly shielded receptacles.

10. Never pipette by mouth.

APPENDIX D (Continued)

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Any injections performed in a non-restricted area should include: removal of absorbent coverings beneath the injection site, wipe test for external contamination, and removal of used alcohol and cotton swabs. Decontaminate and resurvey if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielded containers.

14. Work over surfaces that are easily cleaned or covered with disposable absorbent coverings when handling open solutions of radioactive material. Work only in designated restricted use areas. Process volatile radioactive materials under fume hoods or in glove boxes when possible.

15. Always leave restricted areas secured when trained personnel are not present to assure security over such areas.

16. Treat all work materials and gloves associated with radiopharmaceutical injections and preparations as contaminated until proven otherwise.

APPENDIX E

FACILITY DESIGN CONSIDERATIONS FOR A HOSPITAL'S NUCLEAR MEDICINE DEPARTMENT

1. General

The agency recommends submission of facility plans while still in the design phase. Based on promises of facility completion, the agency may grant approval or make recommendations that can be implemented during the design phase, thereby avoiding costly remodeling and possible over-design.

2. Department Design

The layout of rooms should discourage utilization that promotes unnecessary traffic through restricted areas. Dedicated hot labs (isotope preparation labs), although recommended, would not be necessary for unit-dose-only operations. It would be desirable, however, to isolate reference sources and waste, even if it was only a lockable under-the-sink location. Hot labs should be near injection areas, centralized in larger departments, and access totally restricted to all but trained radiation workers. The ability to separate air circulation between rooms and camera systems associated with Xenon 133 gas, via engineered barriers, will minimize certain limitations and department closures/evacuations. Dedicated patient waiting areas are an ideal way to minimize concerns for public radiation exposure. Stress labs that are to be used as regular injection sites should be situated adjacent to, within, or between two imaging rooms. Clerical and/or office business (e.g., filing, report typing, dictation) should not be carried out in restricted areas. Care should be taken to not place radiographic film bins on walls adjacent to larger radiation sources generating elevated background radiation fields, without plans for shielding. Hand washing sinks should be routinely present. A biological safety cabinet (laminar flow hood) should be utilized in hot labs for preparing sterile radiopharmaceuticals for patient administration, especially when handling open containers of blood specimens.

3. Floor Covering

Floor covering should be composed of a material fostering effective cleaning of solution spills (e.g., heavily waxed tile or linoleum). Carpet is not compatible with decontamination procedures.

4. Work Counters

These surfaces should preferably be stainless steel (especially sinks that might someday be used for releasing radioactive material or decontaminating workers or small equipment). Smooth laminate surfacing however, works adequately in these settings. Unfinished wood or porous building materials that might absorb spilled liquids should not be used. **NOTE:** Most licensees will routinely cover work surfaces with absorbent paper (whose underlining is plastic).

5. Radiation Shielding

Leaded walls are impractical and are rarely used in diagnostic nuclear medicine imaging rooms, hot labs, and stress/treadmill rooms. Lead and/or other suitable shielding materials are commercially available in shielded covers for syringes, vials, trash cans, cabinets/drawers, lined refrigerators, sharps boxes, and small bricks for creating individually shaped counter-top caves. Sheet-lead can also be purchased to line a cabinet and one-quarter inch sheets are usually more than sufficient for routine diagnostic uses. Brachytherapy source storage may require additional lead for adequate shielding of cesium-137, gold-198, or iridium-192.

6. Ventilation

Traditionally, there are two gases of concern in a nuclear medicine lab: therapeutic quantities of iodine-131 (liquid form, once open to air volatilizes, yielding radioactive gas) and xenon-133 (a noble gas). High efficiency particulate air (HEPA) filters provide no serious obstacle for these gases and would not clean air of these contaminates. Activated (heat dried) charcoal filters are traditionally used to remove iodine-131 from a fume hood (associated with iodine-131 solution) and/or to trap xenon-133 gas in a commercial shielded device rather than routinely releasing it to the environment. Rooms where these gases are used should maintain negative pressure in relation to other rooms and corridors.

Iodine-131 concentrations and releases are often unpredictable and engineering controls are a facility's best deterrent to staff or public exposures. Fume hoods are a common location for handling and patient delivery of iodine-131 solution. Glove box operations are only common with commercial suppliers (radiopharmacies) in preparing a capsule form of this radioactive drug. An appropriate trapping filter for exhausted iodine-131 gases from these devices would be an activated charcoal filter. The majority of medical facilities limit their use of iodine-131 to the capsule form, which is routinely considered a contained form and used to avoid personnel exposure, purchase and maintenance of a fume hood and associated filters, and quantifying environmental releases.

Xenon-133 releases will also vary greatly. Prior to licensing a facility, the facility/applicant should submit theoretical calculations demonstrating steady state concentrations (based on average use and worst case release levels) and exponential dilution calculations for establishing the emergency evacuation clearance time following a worst case accident. If the facility is designed such that return air recirculates, they must also show their ability to meet acceptable concentrations throughout the facility. Routine ventilation conditions during xenon use (10 minute patient administration and an additional 30 minutes minimum clearance period) should

comply with the following: a negative pressure differential of 50 to 100 cubic feet per minute, no communicating and/or recirculating air, and dedicated exhaust to a restricted release point that is remote to fresh air intakes (greater than 25 feet). **NOTE:** The higher the exhaust rate, the faster concentrations will return to acceptable levels and evacuated personnel may re-enter. Typically designed exhaust rates for temporary xenon clearance in a single room with a volume of 1600 cubic feet often ranges from 500 to 800 cubic feet per minute removal rate, yielding 20 to 30 room air exchanges per hour. Recirculating air is only discouraged during xenon handling/clearance, and may be engineered for temporary termination or may be rerouted into a dedicated exhaust duct during these periods. The placement of air exhaust and supply registers should move air such that lowest concentrations of contamination might exist at work stations and the room's exit.

7. Security

Locking radioactive material away and securing potentially contaminated areas is necessary if trained staff are not physically present to prevent unauthorized removal or access. In addition, if restricted areas (to include imaging rooms associated stress/treadmill labs) are not comprehensively surveyed at the close of each day to ensure the unrestricted release criteria of §289.202(ggg)(6) [TRCR Appendix 21-F] is not exceeded, personnel from laundry, central supply, maintenance, and housekeeping should not have routine key access to these areas.

8. Waste Disposal Needs

If radioactive waste is intended for routine disposal into the sanitary sewerage system, as is common in an *in vitro* laboratory (that may be directly associated with the main laboratory department), a sink should be dedicated for disposal and decontaminating instruments/containers. This should be posted as to this limited use and drain rapidly to prevent the hold-up or concentration of radioactive solutions.

APPENDIX F

SUGGESTED METHODS FOR COPING WITH SPILLS AND PERSONNEL CONTAMINATION

Facilities using radiopharmaceuticals should maintain a decontamination (DECON) kit to consolidate emergency DECON supplies that might be needed. Supplies for this kit should include necessary items for spill containment, cleaning, disposal packaging, labeling, universal precautions, and area posting needs. When the handler appears to be included in the solution spill, having this kit well labeled and accessible will be paramount. The following are SAMPLE PROCEDURES (excluding volatile airborne and noble gases):

1. Minor Surface Contamination

    a. When contamination appears to involve individuals or multiple locations, notify RSO of the events pending.

    b. If unsure of contamination levels and extent, survey first and verify if removable.

    c. If a single laboratory work surface becomes contaminated, simply remove the work surface's temporary protective covering by rolling or folding the contaminated surface to the middle and place the contaminated covering into labeled plastic bags. Replace temporary protective covering.

    d. If the contamination covers more than a single work surface, don protective garments (double rubber gloves, lab jacket, and shoe coverings) and return with DECON kit and survey instrument. Using the least amount of water possible, (e.g., damp wash-cloths), scrub surfaces. Cleaning efforts should work from the point of lowest to highest contamination. Avoid further spread of contamination and careless handling of contaminated articles by placing all contaminated waste into labeled plastic bags. Initiate detailed surveys (removable and fixed) of the involved surfaces and responders to determine if efforts have been successful or must continue. Abandon efforts after a couple of attempts or when levels can't be further reduced. Carefully survey staff and their protective clothing, removing all waste to storage. Remedial steps may include taping an impermeable cover over any remaining removable contamination and adding shielding to reduce fixed high exposure rates.

2. Major Surface Contamination

    a. Instruct staff nearby not to enter the area, and to phone the RSO for assistance.

    b. Have someone uncontaminated return with the DECON kit and survey instrument.

c. With the RSO's supervision, remove and decontaminate involved persons using universal precautions, bagging contamination and changing outer gloves often. Utilize two persons when possible, one "clean" assistant documenting survey findings and providing supplies, and another performing tasks outlined previously under minor surface contamination. Aggressive surface decontamination may be required and equipment may need to be isolated, secured, and posted for decay-in-storage.

3. Hazardous Contamination (i.e., ruptured sealed therapy sources)

a. Shield the source, but only if able to do so without risk of further contamination or significant radiation exposure.

b. Remove staff and patients at risk. If individuals are believed to be contaminated, contain them in a nearby safe location.

c. Secure all points of access and immediately contact the RSO (if inaccessible, contact his alternate) to manage all further DECON tasks, environmental, and/or facility ventilation considerations. The RSO must assume responsibility and initiate any required contacts with the Texas Department of Health's Bureau of Radiation Control staff via their emergency telephone number. **(512-458-7460)**

d. If fire, explosion, and/or a natural disaster creates a potential hazard of this nature, remove all individuals from harm's way, deal with individual contamination, and warn responders of the associated radiological hazards involved.

4. Personnel Contamination

a. Contamination on any point other than the hands will usually be contained on the clothing.

b. After contaminated clothing is removed, survey the individual to determine if other portions of the body are contaminated.

c. Place contaminated clothing in a labeled plastic bag for storage until such time as radioactive decay assures background levels have been obtained.

d. To decontaminate skin, gently wash with damp cloths soaked in tepid tap water and a mild detergent, and/or irrigate open wounds or eyes that appear contaminated while avoiding spattering or rinsing contaminated wash water onto other bodily areas;

e. Particularly notice if contamination exists on the face or neck area when considering if internal contamination may have resulted and when suspected, nasal wipes and urine samples may yield valuable information.

f. Skin contamination is usually focal and would not indicate whole-body showers. Avoid using hot water and irritating brushes, which tend to increase absorption (internal deposition) through increased vascularity. Often skin contamination cannot be removed. These sites may be wrapped with gauze and with plastic taped over to promote "sweating" the isotope out.

g. If the contaminated individual also has a health condition that necessitates prompt medical treatment, do not delay this treatment. Provide guidance and assistance to the medical caregivers to contain the further spread of any contamination from the individual. Decontamination can proceed after the individual is treated or stabilized.

h. For serious contamination events, advice may be sought from health physicists at Radiological Emergency Assistance Center/Training Site (REAC/TS) in Oak Ridge, Tennessee, (615) 576-3131, or the State's Radiological Emergency Assistance Number (512) 458-7460.

NOTE: FOR ALL CONTAMINATION EVENTS:

1. Document the entire process and associated survey results.

2. Consider risks and potential for internal contamination of all involved.

3. Determine appropriate notifications and reporting based on §289.202(xx) [TRCR 21.1202], §289.202(yy) [TRCR 21.1203], and §289.252(r) [TRCR 41.60].

APPENDIX G

RADIOACTIVE WASTE MANAGEMENT

The following discussion is intended to outline the special considerations of the waste management options in §289.202(ff) [TRCR 21.1001], "General Requirements."

1. Decay in Storage. Decay in storage of radioactive waste must have prior approval from the agency. The following details should be addressed:

   a. Identification of the storage area(s), including labeled containment, posting, area surveying (ambient fields), and security.

   b. Storage of waste a minimum of ten half-lives and appropriate segregation according to half-life.

   c. Surveying of each waste package prior to disposal. The survey should be conducted in a low background area, without shielding, and with a low level instrument. The instrument should be set on its most sensitive setting in combination with a gamma scintillator detector or Geiger-Mueller probe for beta emitters to verify that radiation fields are indistinguishable from background.

   d. Removal, obliteration, or obscuring of radioactive material labels and discarding of the material as non-radioactive wastes.

   e. Documentation of surveys and retention of these records for the life of the license.

   f. Return of radiopharmaceutical residues to the supplying pharmacy for waste processing if the pharmacy is authorized in accordance with §289.254(e) [TRCR 44.6], "Exemptions." These residues reflect only the remaining radioactive material, following use, residing in delivery materials or containers originally dispensed by the pharmacy. Unused radiopharmaceuticals may be transferred to the distributor.

2. Exemptions of Specific Wastes. §289.202(fff)(1) [TRCR 21.1304(a)], "Exemption of Specific Wastes" may address much of the iodine-125, hydrogen-3, and carbon-14 waste (liquid, solid, combined, or research animal) for liquid scintillation counting or laboratory *in vitro* testing. This also includes vials, pipettes, paper and other material in contact with the radioactive materials during the course of the test or experiment. The licensee must perform and maintain documentation of surveys, measurements, and calculations for the life of the license, verifying that the limits were not exceeded.

3. Solid Waste Disposal. Disposal of radioactive waste in a Type 1 municipal solid waste site (landfill) disposal authorized by §289.202(fff)(4) [TRCR 21.1304(d)] requires prior agency approval and must be specifically authorized by license condition. Regulatory Guide 6.6, "Guide for the Preparation of License Amendment Requests for the Disposal of Short-Lived Radioactive Wastes," is available from the agency upon request.

4. Incineration. §289.202(hh) [TRCR 21.1004], "Treatment by Incineration," authorizes a licensee to treat radioactive waste by incineration only in the form and concentration specified in §289.202(fff)(1) [TRCR 21.1304(a)] or as authorized by the agency.

NOTE: Agency requirements are in addition to applicable state rules that may apply (e.g. hazardous, chemical, or biomedical).

APPENDIX H

SAMPLE OF A MINIMUM RADIATION SAFETY OUTLINE FOR RADIATION HANDLERS (TECHNOLOGISTS) IN THE NUCLEAR MEDICINE DEPARTMENT

1. Outline should include the following:

   (1) Instructor(s) qualifications;
   (2) Course syllabus;
   (3) Lesson plan (e.g. how the material is provided to the student);
   (4) Minimum supervisory requirements of the trainee at each phase of on-the-job-training (OJT);
   (5) List of supplied texts and workbooks;
   (6) Testing criteria (quizzes, final exam, and passing score) determining successful completion of each step of the training and tasks mastered. Quizzes following each didactic section and a final examination are suggested.

2. Classroom Training - Format may include lecture and audio/videos. If audio/video training is utilized, it should be less than 50% of the total hours.

Subjects	**Hours**
Radiation physics (atomic structure, modes of decay, interaction with matter, units of dose and activity, conversion of units)	6
Principles of radiation detection and detectors	6
Principles of electronic instruments (pulse-height analyzers, scalers, count-rate meters and computers)	2
Mathematics pertaining to use and measurement of radioactivity (statistics, logarithms, exponentials, decay formula, dilution/concentration, inverse square law)	4
Radiation protection (time, distance, shielding, routes of intake, techniques for radioactive storage and disposal)	4
Radiation biology and measurement techniques (thermoluminescent's, film badges, bioassays)	2
Radiopharmaceutical (preparation, quality control testing, and biodistribution)	4

Subjects	**Hours**
Radiation worker rights and responsibilities (orientation with regulatory and record keeping requirements in the following: §289 [TRCR]; U.S. DOT rules; CFR Parts 171-178; documented radiation protection program; agency approved Operating, Safety, and Emergency Procedures Manual; Clinical Procedures Manual; and Standing Delegation Orders) Clinical Procedures Manual and Standing Delegation Orders are typical names for documents approved by authorized physician users delineating what radiopharmaceutical, the activity, imaging protocol, exam sequence, contra-indications, and under what conditions radiation shall be delivered to a patient.	4

3. Laboratory Training

Subjects	**Hours**
Instrumentation testing (cameras, dose calibrators, scalers and survey instruments)	4
Surveying packages and department, performing decontamination and monitoring procedures.	4
Total Classroom and Laboratory Training	**40 HRS**

4. OJT - OJT should consist of a minimum of three months training and should be a full-time commitment, averaging a minimum of four exams per day. The OJT period may extend up to six months or longer depending on the scope of the program and the abilities of the trainee. During the OJT, the trainer should document and sign-off on the trainee's mastery of all procedures (detection equipment, clinical testing, radiation protection, surveys, and packaging.) The following minimum OJT may be followed unless extended periods are deemed necessary by the trainer:

   a. Observation of procedures - two weeks.
   b. Performance of procedures with trainer in room - two weeks.
   c. Performance of procedures with trainer accessible within the building - two months.

5. Trainer Credentials

   a. Didactic Trainer. The following individuals or combination of individuals are suggested as didactic trainers:

      (i) Authorized physician user.
      (ii) Board certified nuclear pharmacist.
      (iii) Certified Health Physicist (CHP).
      (iv) Licensed medical physicist with specialty in health physics or nuclear medicine.
      (v) Nuclear medicine technologist, CNMT or ARRT(N), with five years experience.

   b. On-The-Job-Trainer. The following individuals or combination of individuals are suggested as on-the-job-trainers:

      (i) Authorized physician user.
      (ii) Licensed medical physicist with specialty in medical health physics or nuclear medicine.
      (iii) Nuclear medicine technologist, CNMT or ARRT(N), with one year experience.
      (iv) RSO.
      (v) Board certified nuclear pharmacist could supervise some aspects of training as appropriate.

6. OJT Period - The training period should be a full-time commitment if the work-load supports such (e.g., averaging at least four exams/day). In addition to the number of procedures, considerations should include the complexity of program, and scope of practices and delegated tasks. Assuming a simple unit-dose, diagnostic only practice performing only the most common procedures, three months (equivalent to 480 hours) of laboratory practices would be expected. No licensed program averaging less than ten exams a week should consider an in-house training program. The OJT period may run as long as six or even 12 months depending of the scope of program and/or infrequency of exams due to low referral numbers.

7. Trainee Evaluation - Multiple quizzes (one with each didactic section), a final exam, and trainer signed-off recognition of successful mastery for the various tasks expectations, will demonstrate successful trainee comprehension. Any trainee testing yielding unacceptable scores, must include documentation of remedial training and successful retesting.

8. Record Keeping Requirements - The following records should be maintained:

   a. Classroom attendance sheets identifying trainee, dates, time, and signature of trainer.
   b. Credentials of didactic and on-the job trainers.
   c. All graded quizzes and final exam.
   d. Copy of certificate and/or document indicating successful completion of training with original going to the trainee.

APPENDIX I

SAMPLE PROCEDURES FOR CALIBRATION OF DOSE CALIBRATORS

The following sample procedures may be used for checking and testing dose calibrators.

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)

    a. Constancy at least once each day prior to assay of patient dosages (± 5.0%).

    b. Linearity at installation and at least quarterly thereafter (± 5.0%).

    c. Geometry dependence at installation (± 5.0%).

    d. Accuracy at installation and at least annually thereafter (± 5.0%).

2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as cesium-137, cobalt-60, cobalt-57, or radium-226 using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

    a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the cesium-137 setting to assay cesium-137).

    b. Measure background at the same setting and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

    c. For each source used, either put on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.

    d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or the authorized physician user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. Repair or replace if the error exceeds 10%.

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of technetium-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

   a. Decay Method

      (i) Assay the technetium-99m syringe or vial in the dose calibrator and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form (See Attachment 1). This first assay should be done in the morning at a regular time, for example, 8:00 a.m.

      (ii) Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

      (iii) Convert the time and date information you recorded to hours elapsed since the first assay.

      (iv) On a sheet of semilog graph paper or on a copy of the sample form in Attachment 1, label the form in Attachment 1, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date, the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.

      (v) Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.
      (A-observed - A-line)/A-line = deviation.

(vi) If the worst deviation is more than ± 0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

(vii) Put a sticker on the dose calibrator that says when the next linearity test is due.

b. Shield Method

(i) If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them. Begin the linearity test as described in the decay method described above. After the first assay, the sleeves can be calibrated as follows. (Steps (A) through (C) below must be completed within six minutes.)

(A) Put the base and sleeve one in the dose calibrator with the vial. Record the sleeve number and indicated activity.

(B) Remove sleeve one and put in sleeve two. Record the sleeve number and indicated activity.

(C) Continue for all sleeves.

(D) Complete the decay method linearity test steps (A) through (F) above.

(E) From the graph made in step (iv) of the decay method, find the decay time associated with the activity indicated with sleeve one in place. This is the "equivalent decay time" for sleeve one. Record that time with the data recorded in step (A).

(F) Find the decay time associated with the activity indicated with sleeve two in place. This is the "equivalent decay time" for sleeve two. Record that time with the data recorded in step (B).

(G) Continue for all sleeves.

(H) The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

(ii) The sleeve set may now be used to test dose calibrators for linearity.

(A) Assay the technetium-99m syringe or vial in the dose calibrator, and subtract the background to obtain the net activity in millicuries. Record the net activity.

(B) Steps (C) through (E) below must be completed within six minutes.

(C) Put the base and sleeve one in the dose calibrator with the vial. Record the sleeve number and indicated activity.

(D) Remove sleeve one and put in sleeve two. Record the sleeve number and indicated activity.

(E) Continue for all sleeves.

(F) On a sheet of semilog graph paper or on a copy of the sample form in Attachment 1, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date, model number, and serial number of the dose calibrator.

(G) Plot the data using the equivalent decay time associated with each sleeve.

(H) Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.
(A-observed - A-line)/A-1ine = deviation.

(I) If the worst deviation is more than ± 0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

(J) Put a sticker on the dose calibrator that says when the next linearity test is due.

6. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3 cubic centimeter (cc) plastic syringes and that radiopharmaceutical kits are made in 30 cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

a. ln a small beaker or vial, mix 2 cubic centimeters of a solution of technetium-99m with an activity concentration between 1 and 10 millicuries/milliliter. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.

b. Draw 0.5 cubic centimeters of the technetium-99m solution into the syringe and assay it. Record the volume and mi11icuries indicated on the Dose Calibrator Geometry and Accuracy Form (See Attachment 2).

c. Remove the syringe from the calibrator, draw an additional 0.5 cubic centimeters of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated and assay again.

d. Repeat the process until you have assayed a 2.0 cubic centimeters volume.

e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5.0% error lines above and below the chosen "standard volume."

f. If any correction factors are greater than .05 or less than 0.95 or if any data points lie outside the 5.0% error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence" and note the date of the test, model number, and serial number of the calibrator.

g. To test the geometry dependence for a 30 cubic centimeter glass vial, draw 1.0 cubic centimeters of the technetium-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cubic centimeters of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

i. Repeat the process until you have assayed a 19.0 cubic centimeters volume. The entire process must be completed within ten minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5.0% error lines above and
below the chosen "standard volume."

k. If any correction factors are greater than .05 or less than 0.95 or if any data points lie outside the 5.0% error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence" and note the date of the test, model number, and serial number of the calibrator.

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as cobalt-57, cobalt-60, or cesium-137) should be used.

   a. Assay a calibrated reference source at the appropriate setting (i.e., use the cobalt-57 setting to assay cobalt-57) and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on the Dose Geometry and Accuracy Form (See Attachment 2). Repeat for a total of three determinations.

   b. Average the three determinations. The average value should be within 5.0% of the certified activity of the reference source, mathematically corrected for decay.

   c. Repeat the procedure for other calibrated reference sources.

   d. If the average value does not agree, within 5.0%, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. If the error exceeds 10%, it is suggested that the unit be repaired or replaced.

   e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

   f. Put a sticker on the dose calibrator that says when the next accuracy test is due.

8. The RSO should review and sign the records of all geometry, linearity, and accuracy tests. See Attachments 1 and 2 for some forms you may want to use.

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REGULATORY GUIDE 3.1
GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE MEDICAL USE OF RADIOACTIVE MATERIAL